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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/755,427

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Lee Bolduc

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EXAMINER

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ART UNIT

PAPER NUMBER

3734

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/755,427	<b>Applicant(s)</b> BOLDUC ET AL.	
	<b>Examiner</b> Diane Yabut	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006; 27 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/8/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statements (IDS) submitted on 8 March 2004 and 15 December 2005 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kapitanov** (U.S. Patent No. **4,204,541**).

Claim 1: Kapitanov discloses an applicator for attaching fasteners to body tissue comprising a distal portion having an elongate outer tube **1**, a connecting end and a terminal end, a proximal portion having a handle and an actuator **13**, the proximal portion being attached to the connecting end of the distal portion, and a rotator **10** cooperating with the actuator **13** and including a longitudinal groove extending along at least a portion of the length of the rotator **10**, the groove configured to receive a portion of a fastener **2** wherein the rotator resides within and extends substantially the length of

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the outer tube **1** such that the actuation of the actuator **13** rotates the fastener **2** relative to the outer tube **1** (Figures 1-2, col. 4, lines 3-12).

Claim 6: Kapitanov discloses a nose piece (at the distal end of element **8** where **13** is the proximal end) attached to the terminal end, the nose piece having structure projecting perpendicularly toward a longitudinal axis of the outer tube and adapted to engage the plurality of fasteners (Figure 1).

Claim 7: Kapitanov discloses the distal portion and the proximal portion being releasably secured together (col. 3, lines 32-34).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kapitanov** (U.S. Patent No. **4,204,541**) in view of **Smith et al.** (U.S. Patent No. **4,596,350**).

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Claims 2 and 3: Kapitanov discloses the claimed device except for a lock/clip indicator for engaging a plurality of fasteners which is configured to prevent actuation of the actuator upon discharge of the plurality of fasteners from the applicator, and a load spring for applying longitudinal forces against the lock/clip indicator.

Smith et al. teaches a lock/clip indicator **51** for engaging a plurality of fasteners which is configured to prevent actuation of the actuator upon discharge of the plurality of fasteners from the applicator, and a load spring **20** for applying longitudinal forces against the lock/clip indicator (col. 9, lines 35-52). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a lock/clip indicator and load spring, as taught by Smith et al., to Kapitanov since it was known in the art that lock/clip indicators with spring mechanisms stops undesirable forward advancement of fasteners.

6. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kapitanov** (U.S. Patent No. **4,204,541**) in view of **Hooven et al.** (U.S. Patent No. **5,433,721**).

Claims 4 and 5: Kapitanov discloses the claimed device except for a thread form contained in an interior of the terminal end adapted to engage the plurality of fasteners and being an interlock spring fixedly retained in the interior of the terminal end.

Hooven et al. teaches a thread form contained in an interior of the terminal end adapted to engage the plurality of fasteners and being an interlock spring fixedly retained in the interior of the terminal end, wherein "spring" is taken to mean an "actuating force" (Figure 12). It would have been obvious to one of ordinary skill in the

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art at the time of invention to provide an interior thread being an interlock spring form, as taught by Hooven et al., to Kapitanov since it was known in the art that thread form structures are used to engage helical, coil-like structures.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kapitanov** (U.S. Patent No. **4,204,541**) in view of **Green et al.** (U.S. Patent No. **5,100,420**).

Claim 8: Kapitanov discloses the claimed device except for the distal portion being disposable and the proximal portion being reusable.

Green et al. teaches a distal portion being disposable and the proximal portion being reusable (col. 10, lines 47-51). It would have been obvious to one of ordinary skill in the art to provide a disposable distal portion and a reusable proximal portion, as taught by Green et al., to Kapitanov since it was known in the art that disposable distal portions of medical devices is a solution to time-consuming sanitation of the distal ends prior to being introduced into the body.

8. Claims 9, 11-14, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kapitanov** (U.S. Patent No. **4,204,541**) in view of **Pratt et al.** (U.S. Patent No. **5,607,436**).

Claims 9 and 14: Kapitanov discloses the claimed device except for a lever with a first end, a midsection, and a second end, a lead screw, and a nut driver.

Pratt et al. teaches a lever **14** having a first end, a midsection, and a second end, the lever pivotally attached about a midpoint to the handle, the first end of the lever for gripping by hand, a lead screw **54** rotatably attached to interior of the handle, a nut

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driver, the second end of the lever pivotally attached to the nut driver, the nut driver for traveling along the lead screw, thereby turning the lead screw, and the lead screw attached to the rotator so that as the lever is depressed by hand the nut driver will travel along the lead screw towards the rotator thereby turning the rotator in the process (Figures 3-7). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a first end, a midsection, and a second end, a lead screw, and a nut driver with all the above limitations, as taught by Pratt et al., to Kapitanov since it was known in the art to use lever, screw, and driver mechanisms to advance fastening members from the interior of an applicator to the exterior.

Claim 11: Kapitanov discloses the claimed device except for the lever having a midsection extension.

Pratt et al. teaches a lever having a midsection extension **36** (Figure 3). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a midsection extension, as taught by Pratt et al., to Kapitanov since it was known in the art that midsection extensions on levers are used in order to engage with the proximal, driver portion of the applicator.

Claims 12, 13, 16 and 18: Kapitanov discloses the claimed device except for gear teeth formed within the interior of a handle, a spring loaded pawl pivotally attached to the midsection extension and adapted to engage the gear teeth, the releasable engagement means being a ratchet mechanism, and a latch pawl cooperating with the teeth to prohibit the lever from backstroking until it has been completely depressed.

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Pratt et al. teaches gear teeth **48** formed within the interior of a handle, a spring loaded pawl **40** pivotally attached to the midsection extension and adapted to engage the gear teeth, the releasable engagement means being a ratchet mechanism (Figure 3). It would have been obvious to one of ordinary skill in the art to provide the ratchet mechanism including the gear teeth and spring loaded pawl, as taught by Pratt et al., to Kapitanov since it was known in the art to use ratchet mechanisms to restrict movement in one direction.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kapitanov** (U.S. Patent No. **4,204,541**) in view of **Knodel et al.** (U.S. Patent No. **5,487,500**).

Claim 17: Kapitanov discloses the claimed device, including having a mid-section extension, except for formed in the mid-section extension are a plurality of teeth.

Knodel et al. teaches a mid-section extension with formed plurality of teeth (Figure 6). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a plurality of teeth, as taught by Knodel et al., to Kapitanov's mid-section extension since it was known in the art that teeth are used in ratchet and gear mechanisms which are used in applicators.

10. Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kapitanov** (U.S. Patent No. **4,204,541**).

Claims 10 and 15: Kapitanov discloses the claimed device except for the lead screw being a high helix lead screw. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a high helix lead screw for the lead screw in

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Kapitanov since it was known in the art that high helix angle thread screws are high efficiency using low rotational speeds.

***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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